

## REMARKS

Claim 17 was found to be allowable if written in independent form including all of the limitations of its base claim. Claim 17 recites that the botanical material comes from *Rosemarinus officinalis* and that the natural organic component extracted by the method has antioxidant activity enhanced over extraction by TFE alone.

Claims 1-16, 20 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make or use the invention. The Section 112 rejection is traversed in light of amendments that have been made to the claims to limit them to botanical material of Labiatae species which are known to produce the antioxidant compounds carnosol, carnosic acid, rosmanol and/or rosmarinic acid.

As pointed out by the Examiner, the examples in the specification of the application are limited to the extraction of botanical material collected from plants of the species *Rosemarinus officinalis*. There is nothing inherent in the claimed process, however, that limits it to the extraction of organic compounds from botanical material of plants of a particular species and anyone skilled in the art would immediately recognize that the process could be applied to extract organic components from a wide variety of plants. This level of skill in the art is amply supported in the record in this application by the specification and numerous prior art references that have been provided and made of record, as well as the ICI reference, the Kimura reference, and the Advanced Phytonics reference (each of which are discussed in detail below), which teach the extraction of organic molecules from a variety of plant sources using a variety of processes each of which, though distinct from the present process, is applied uniformly in each reference across plants of diverse species with results which are used for comparison purposes.

The present claims have been limited to the production of an extract with antioxidant activity. The specification recites numerous examples in the literature where carnosol, carnosic acid, rosmanol and/or rosmarinic acid have been identified as the major active antioxidant compounds in rosemary. Those skilled in the art recognize that these compounds are secondary metabolites that are part of a chemical cascade mediated by enzymes which are common across a variety of plants of Labiatae species, and that extracts of a number of the species exhibit comparable antioxidant activity. Economou, K.D.; Oreopoulou, V.; and Thomopoulos, C.C., Antioxidant Activity of Some Plant Extracts of the Family Labiatae, J. Am. Oil Chem. Soc., 1991, 68, 109-113; Zandi, P.; Ahmadi, L., Antioxidant Effect of Plant Extracts of Labiatae Family, J. Food Sci. Technol., 2000, 37, 436-439.

The following published materials disclose that the identified plant species are sources of carnosol, carnosic acid, rosmanol and/or rosmarinic acid:

Basil (*Ocimum basilicum*) – Fitoterpia No. 62: 166; Phytochemical Database, USDA-ARS-NGRL, Beltsville Agricultural Center, Beltsville, Maryland 20705.

Heal-All, Self-Heal (*Prunella vulgaris*) – Yakugaku Zasshi, 106: 1108; Phytochemical Database, USDA-ARS-NGRL, Beltsville Agricultural Center, Beltsville, Maryland 20705.

Hyssop (*Hyssopus officinalis*) – Djarmati, Z.; Jankov, R.M.; Schwirtich, E.; Djulinac, B.; Djordjevic, A. High Antioxidant Activity of Extracts Obtained from Sage by Supercritical CO<sub>2</sub> Extraction. J. Am. Oil Chem. Soc., 1991, 68, 731-734.

Lavender (*Lavandula angustifolia*) – Fitoterpia No. 62: 166; Phytochemical Database, USDA-ARS-NGRL, Beltsville Agricultural Center, Beltsville, Maryland 20705.

Marjoram (*Origanum majorana*) – Fitoterpia No. 62: 166; Phytochemical Database, USDA-ARS-NGRL, Beltsville Agricultural Center, Beltsville, Maryland 20705.

Mint (*Mentha* sp.) – Fitoterpia No. 62: 166; Phytochemical Database, USDA-ARS-NGRL, Beltsville Agricultural Center, Beltsville, Maryland 20705.

Oregano (*Origanum vulgare*) – Fitoterpia No. 62: 166; Phytochemical Database, USDA-ARS-NGRL, Beltsville Agricultural Center, Beltsville, Maryland 20705.

Sage (*Salvia officinalis*) – Cuvelier, M.E.; Berset, C.; Richard, H. Antioxidant Constituents in Sage (*Salvia officinalis*). J. Agric. Food Chem., 1994, 42, 665-669.

Thyme (*Thymus vulgaris*) – Fitoterpia No. 62: 166; Phytochemical Database, USDA-ARS-NGRL, Beltsville Agricultural Center, Beltsville, Maryland 20705.

Clearly, many researchers have identified antioxidant components of plants from Labiatae species and have used a variety of extraction processes to evaluate and measure the antioxidant activity of extracts of these plants. The present process improves the antioxidant activity of the extract over and extract produced using TFE alone. Those skilled in the art will readily recognize that the present process, demonstrated to be effective when used to extract rosemary plants, is applicable to other plants which contain significant amounts of the active antioxidant compounds of rosemary. The claims have been amended to recite that the botanical material used in the extraction process is taken from plants of species which the literature recognizes contain the recognized principal antioxidant compounds of rosemary, namely carnosol, carnosic acid, rosmanol and/or rosmarinic acid. It is respectfully requested that the rejection under Section 112 of claims 1-16, 20 and 21, be reconsidered and withdrawn in light of the amendments made to the claims and these remarks.

The present application was filed under the Patent Cooperation Treaty and an International Search Report and Written Opinion have been received (a copy of each are enclosed with this Preliminary Amendment). Claims 1-3, 9, and 13-15 have been rejected as

2, 3, lacking novelty as being anticipated by PCT Application WO 95/26794, applicant Imperial Chemical Industries (hereinafter referred to as "ICI"). Claims 1-19 have been rejected as being obvious over the ICI application in view of Kimura et al. (U.S. Patent 4,380,506). Additionally, pending application GB 2 234 050, applicant Advanced Phytonics Limited (hereinafter referred to as "Advanced Phytonics"), was cited in the International Search Report as being relevant to the claims but having a publication date prior to the international filing date of the PCT application, but later than the filing date of the present U.S. patent application. These references as well as others that have come to the attention of applicant are included in a Supplemental Invention Disclosure Statement filed contemporaneously with this Preliminary Amendment.

Applicant respectfully disagrees with the rejections made in the International Search Report and proffers these remarks in the present case in support of the patentability of the present claims over these references.

The ICI application teaches the use of TFE and a co-solvent to extract a component, namely a fragrance or aromatic oil, from plant material. TFE, of course, is a gas at room temperature. The co-solvent in the ICI application is selected also to have a relatively low boiling point so that once the extraction process is completed, the extraction solvents can be removed by distillation at room temperature and below (page 7, first paragraph). ICI teaches that the co-solvent should have a boiling point preferably below 20°C and that suitable co-solvents are aliphatic or alicyclic hydrocarbons in the range of C<sub>2-6</sub>, and preferably C<sub>2-4</sub>, and hydrocarbon ethers. The only specific co-solvents provided are ethane, n-propane, i-propane (*sic*, no such compound exists), n-butane, i-butane, dimethyl ether, methyl ethyl ether, and diethyl ether (page 5 of the application). The reason for the selection of these co-solvents is that ICI wanted to keep the boiling point of the co-solvents as low as possible so the removal of the extraction solvents

would be “relatively facile allowing the distillation to be carried out at relatively low temperatures, e.g., room temperature and below. This in turn reduces the risk of losing (*sic*) desired product either through co-evaporation of the more volatile compounds with the extraction solvent or thermal degradation of the more thermally unstable compounds.” (Page 7 of the application.)

-In contrast, the present application describes co-solvents that are intentionally left behind when the TFE is distilled at room temperature. The preferred co-solvent acetone has a boiling point of 56.2°C, the preferred co-solvent methanol has a boiling point of 64.5°C, and the co-solvent hexane has a boiling point of 68.7°C (room temperature being approximately 20 – 22°C). The antioxidant compounds sought to be extracted in the present invention are polar molecules that are retained in the co-solvent(s) after the TFE has been distilled off so that they can be extracted under higher temperature distillation in a separate step to yield a commercially useful extract containing a high amount of the antioxidant compounds and, importantly, little or none of the volatile fragrances that are specifically sought by ICI. Indeed, it is important to the commercial acceptability of the antioxidant extract of the present invention that it contain as little as possible of the fragrant components of the plant being extracted as these antioxidant extracts are most commonly used to stabilize foods and any fragrant compounds present will add an undesired odor and flavor component to the food being treated. The very purpose of the ICI extraction process, to generate an extract containing the fragrance components, is therefore directly opposite to that of the present process, thus evidencing the patentable distinctiveness of the present process over that described in the ICI reference.

Kimura teaches a method of simultaneously extracting both antioxidant and antibacterial components of herbs using a mixture of polar and non-polar solvents. The non-polar solvents

identified in the specification are n-hexane, petroleum ether, ligroin, cyclohexane, carbon tetrachloride, chloroform, dichloromethane, 1,2-dichloroethane, toluene, and benzene. A requirement of the Kimura process is that the non-polar solvent must be a liquid at room temperatures and pressures because the extraction is carried out at room temperatures and pressures over an extended period of time (column 5, lines 20-25) and the active fraction that is sought to be recovered is dissolved in the non-polar solvent while the polar solvent is removed by washing of the reaction mixture with water (column 5, lines 30-68). Kimura teaches nothing whatsoever about the use of TFE as a solvent or the use of any co-solvent in combination with TFE. No part of the Kimura process, moreover, is applicable to the process of the present invention. There is nothing in Kimura that can be asserted to make obvious to one skilled in the art the distinctive process described and claimed in the present invention.

The Advanced Phytonics application under was filed the Patent Cooperation Treaty on April 8, 1998. Under 35 U.S.C. 102(e), the Advanced Phytonics reference is not prior art as to the present application if the invention of the present application was made prior to the filing date of the PCT application. The declaration of James Haworth, John A. Greaves and Friedhelm Brinkhaus, the three inventors of the present application, are submitted with this Amendment to swear behind the Advanced Phytonics reference. The declaration recites facts which demonstrate that the present invention was conceived and reduced to practice prior to the April 8, 1998, filing date of the PCT application. As such, the Advanced Phytonics reference is removed as effective prior art against the present invention.

Claims 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite due to the use of the phrase "substantially similar". In accordance with the suggestion of the

Examiner, this word has been deleted from claim 11 and claim 13 has been cancelled.

Reconsideration and withdrawal of this ground of rejection is respectfully requested.

The application has been amended to correct minor informalities, to further distinguish the application over the prior art, and to more particularly point out and distinctly claim the subject matter which Applicant regards as the invention so as to place the application, as a whole, into a prima facie condition for allowance. Great care has been taken to avoid the introduction of new subject matter into the application as a result of the foregoing modifications.

Accordingly, the purpose of the claimed invention is not taught nor suggested by the cited references, nor is there any suggestion or teaching which would lead one skilled in the relevant art to combine the references in a manner which would meet the purpose of the claimed invention. Because the cited references, whether considered alone, or in combination with one another, do not teach nor suggest the purpose of the claimed invention, Applicant respectfully submits that the claimed invention, as amended, patentably distinguishes over the prior art, including the art cited merely of record.

Based on the foregoing, Applicant respectfully submits that its claims 1-12, 15 and 18-21, as amended, are in condition for allowance at this time, patentably distinguishing over the cited prior art. Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to call the undersigned attorney at (515) 288-2500 to discuss the claims in an effort to reach a mutual agreement with respect to claim limitations in the present application which will be effective to define the patentable subject matter if the present claims are not deemed to be adequate for this purpose.

Respectfully submitted,

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